E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0004; FRL-11246-01-OCSPP]

Pyraclonil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyraclonil in or on rice, grain. Nichino America, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Objections and requests for hearings must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0004, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email

address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2020-0004 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Addresses for mail and hand delivery of objections and hearing requests are

provided in 40 CFR 178.25(b), although the Office of Administrative Law Judges encourages parties to file electronically. *See https://www.epa.gov/sites/default/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf*.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0004, by one of the following methods:

• *Federal eRulemaking Portal*: *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the ***Federal Register*** of March 3, 2020 (85 FR 12454) (FRL-10005-58), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8809) by Nichino America, Inc., 4550 Linden Hill Road, Suite 501, Wilmington, DE 19808. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide pyraclonil, 1-(3-chloro-4,5,6,7-tetrahydropyrazolo[1,5-*a*]pyridin-2-yl)-5-[methyl(prop-2-ynyl)amino]pyrazole-4-carbonitrile, in or on rice, grain at 0.01

parts per million (ppm). That document referenced a summary of the petition prepared by Nichino America, Inc., the registrant, which is available in the docket *https://www.regulations.gov*. Three comments supporting the registration were improperly filed in the docket for the notice of filing (NOF); there were no comments on the tolerance action.

Based upon review of the data supporting the petition, EPA has recommended changes to the tolerance expression. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyraclonil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyraclonil follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major

identifiable subgroups of consumers, including infants and children.

The target organs of pyraclonil are the liver and the thyroid. Liver effects were found to be primarily adaptive (increased weight, hepatocellular hypertrophy, induction of cytochrome P450); however, female mice showed adverse liver effects (clinical chemistry changes, increased liver weight, and fat deposits after 90 days of oral exposure; these initial changes progressed to cellular alteration, liver masses, and hepatocellular adenomas after 78 weeks of oral exposure). Thyroid effects occurred in rats at similar doses across the database via oral exposures (lowest observed adverse effect levels (LOAELs) range from 74 to 207 mg/kg/day). Thyroid follicular cell hypertrophy was observed in both sexes of rats in several studies, after 14 or more days of oral exposure. Colloid degeneration was observed in both sexes, and thyroid follicular cell adenomas were observed in males in a chronic study. Increased blood levels of thyroid stimulating hormone (TSH) and decreased levels of thyroxine (T4) were detected after 1, 2, 52, and 104 weeks of oral exposure (hormones only measured in one 14-day oral study and one chronic study), in either or both sexes. No thyroid effects were detected in mice or dogs.

No reproductive effects were detected. No increased pre- or postnatal susceptibility was detected. Pup weights were decreased in the rat reproductive study at the same dietary concentration at which thyroid effects were observed in adults. Decreased fetal weights were seen in a rat developmental study at the same dose as maternal clinical signs and decreased body weight. In an acute neurotoxicity study, decreased motor activity and several functional observation battery (FOB) findings (tremors, hunchback posture and slight lacrimation; decreased alertness, exploration, approach response and landing foot splay; and decreased body temperature) were noted only at 2 hours post-dosing with a single dose of 400 mg/kg in females, and at higher doses in males. There was no effect of treatment on neurological parameters measured in a 90-day repeat dose studies in the rat.

Pyraclonil is classified as “Likely to be Carcinogenic to Humans”, based on treatment-related hepatocellular tumors in female mice (adenomas and combined adenomas/carcinomas),

and thyroid follicular cell tumors in male rat (adenomas and combined adenomas/carcinomas). The unit risk, Q1* $(mg/kg/day)^{-1}$ of pyraclonil based upon female mouse liver tumor rates is 1.08 x 10^{-2} in human equivalents.

Specific information on the studies received and the nature of the adverse effects caused by pyraclonil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *https://www.regulations.gov* in document Pyraclonil. Human Health Risk Assessment for the New Active Ingredient for use on Rice at 11-14 in docket ID number EPA-HQ-OPP-2020-0004.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides*.

A summary of the toxicological endpoints for pyraclonil used for human risk assessment can be found on pages 18-20 in the Pyraclonil Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to pyraclonil, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from pyraclonil in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for pyraclonil. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2005-2010 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA conducted an unrefined acute dietary exposure assessment for the proposed new use on rice and assumed 100 percent crop treated (PCT), tolerance-level residues and default processing factors.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2005-2010 NHANES/WWEIA. As to residue levels in food, EPA conducted an unrefined chronic dietary exposure assessment for the proposed new use on rice and assumed 100 PCT, tolerance-level residues and default processing factors.

iii. *Cancer*. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that pyraclonil should be classified as “Likely to be Carcinogenic to Humans” and a

linear approach has been used to quantify cancer risk. The inputs for the cancer dietary exposure assessment and the chronic dietary exposure assessment were equivalent with the exception of the estimated drinking water concentrations (EDWC) used. Applying the Q1* of 1.08 x 10^{-2} (mg/kg/day)-1 to the exposure value (0.000136 mg/kg/day) results in a cancer risk estimate of 1 x 10^{-6} for adults 20 to 49 years old.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for pyraclonil. Tolerance level residues and/or 100PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyraclonil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyraclonil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment*.

Based on the Pesticides in Flooded Application Model (PFAM version 2.0), the maximum EDWCs of 50.8 µg/L for the 1-in-10-year daily mean, 6.68 µg/L for the 1-in-10-year annual mean, and 6.40 µg/L for the 30-year annual mean concentration in surface water were used in the acute, chronic, and cancer analyses, respectively.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Pyraclonil is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism

of toxicity."

EPA has not found pyraclonil to share a common mechanism of toxicity with any other substances, and pyraclonil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyraclonil does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. No increased pre- or postnatal susceptibility was detected in developmental studies in rats or rabbits, or in a reproductive study in rats.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for pyraclonil is complete.

ii. Potential evidence of neurotoxicity was observed in the pyraclonil acute neurotoxicity study; however, concern is low since a clear NOAEL was established and the selected endpoints are protective of the observed effects.

iii. There is no evidence that pyraclonil results in increased susceptibility *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT, tolerance-level residues and default processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyraclonil in drinking water. These assessments will not underestimate the exposure and risks posed by pyraclonil.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyraclonil will occupy <1% of the aPAD for all infants <1 year old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyraclonil from food and water will utilize <1% of the cPAD for all infants <1 year old, the population group receiving the greatest exposure There are no residential uses for pyraclonil.

3. *Short-term and Intermediate-term risk*. Short-term and Intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short-term and intermediate-term adverse effect was identified; however, pyraclonil is

not registered for any use patterns that would result in short-term or intermediate-term residential exposure. Short-term or intermediate-term risk is assessed based on short-term or intermediate-term residential exposure plus chronic dietary exposure. Because there is no short-term or intermediate-term residential exposure, and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term and intermediate-term risk), no further assessment of short-term or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term and intermediate-term risk for pyraclonil.

4. *Aggregate cancer risk for U.S. population*. The estimated exposure of adults 20 to 49 years old (the most highly exposed adult subpopulation) to pyraclonil is 0.000136 mg/kg/day. Applying the Q1* of 1.08 x 10-2 (mg/kg/day)-1 to the exposure value results in a cancer risk estimate of 1 x 10-6 for adults 20 to 49 years old. EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or x 10^{-6}) or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the logarithmic scale; for example, risks falling between 3 x 10^{-7} and 3 x 10^{-6} are expressed as risks in the range of 10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. The pyraclonil exposure assessment is unrefined and retains significant conservatism in that tolerance-level residues and 100 percent crop treated is assumed for the rice use. In addition, EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyraclonil in drinking water. These assessments will not underestimate the exposure posed by pyraclonil. Accordingly, EPA has concluded the aggregate cancer risk for all existing pyraclonil uses and the new uses in this action fall within the range of 1×10^{-6} and are thus negligible.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and

children from aggregate exposure to pyraclonil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology such as high-performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS), Method GLP-MTH-108, is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for pyraclonil.

C. Revisions to Petitioned-For Tolerances

The Agency is establishing a tolerance for residues of pyraclonil expressed as: (1-(3-chloro-4,5,6,7-tetrahydropyrazolo[1,5-*a*]pyridin-2-yl)-5-(methyl-2-propyn-1-ylamino)-1*H*-pyrazole-4-carbonitrile), which is the CAS name, rather than the petitioned for expression of pyraclonil: 1-(3-chloro-4,5,6,7-tetrahydropyrazolo[1,5-*a*]pyridin-2-yl)-5-[methyl(prop-2-

ynyl)amino]pyrazole-4-carbonitrile, which is the IUPAC name.

V. Conclusion

Therefore, tolerances are established for residues of pyraclonil, 1-(3-chloro-4,5,6,7-tetrahydropyrazolo[1,5-*a*]pyridin-2-yl)-5-(methyl-2-propyn-1-ylamino)-1*H*-pyrazole-4-carbonitrile, in or on rice, grain at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct

effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the ***Federal Register***. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 16, 2023.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.725 to subpart C to read as follows:

§ 180.725 Pyraclonil; tolerances for residues.

(a) – (b) [Reserved]

(c) *Tolerances with regional registrations*. Tolerances are established for residues of the herbicide pyraclonil, including its metabolites and degradates, in or on the commodities to the table to this paragraph (c). Compliance with the tolerance levels specified in the table to this paragraph (c) is to be determined by measuring only pyraclonil (1-(3-chloro-4,5,6,7-tetrahydropyrazolo[1,5-*a*]pyridin-2-yl)-5-(methyl-2-propyn-1-ylamino)-1*H*-pyrazole-4-carbonitrile).

Table 1 to Paragraph (c)

Commodity	Parts per million
Rice, grain	0.01

(d) [Reserved]

[FR Doc. 2023-18181 Filed: 8/23/2023 8:45 am; Publication Date: 8/24/2023]